Quantative Angiographic Analysis

Variable (Number of Lesions)	EES (N=22)	MS (N=43)	P-value
Reference Diameter, mm	2.91±0.33	2.97±0.54	0.6
Final MLD, mm	2.88±0.29	2.87±0.42	0.9
Acute Gain, mm	1.83±0.52	1.83±0.42	1.0
FU Stent MLD, mm	2.74±0.28	2.02±0.74	<0.0001
FU Prox Stent Edge MLD, mm	2.65±0.66	2.66±0.64	1.0
FU Distal Stent Edge MLD, mm	2.43±0.47	2.36±0.53	0.6
Stent Late Loss, mm	0.12±0.28	0.85±0.58	<0.0001
Stent Restenosis, %	0.0%	19.4%	0.04
Segment Restenosis, %	4.8%	30.6%	0.04
Target Vessel Revascularization, %	0.0%	7.5%	0.5
MACE, %	4.8%	17.5%	0.2

2:30 p.m.

843-3

Late Quantitative Angiographic Results Following Treatment With a Polymer-Based Paclitaxel-Eluting Stent Compared With a Bare Metal Stent in Patients With De Novo Coronary Disease: The TAXUS-IV Angiographic Results

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Background: A reduction in restenosis has been shown with paclitaxel-eluting stents in patients with focal stenoses in native coronary arteries, but the benefit of these stents has not been shown in more complex lesion subsets.
Methods: The TAXUS-IV study randomized 1,326 patients with complex coronary stenosis to single vessel treatment with the paclitaxel-eluting or bare metal Express™ stent. Of these, 732 patients were assigned to 9 month angiographic follow-up and late repeat angiography was performed in 559 (76.4%) of these patients. Quantitative angiographic analysis (CMS, Medis) was performed at baseline, after the stent procedure and at late angiographic follow-up. Analysis of the lumen changes within the stent (IS), its 5-mm proximal and distal edges, and within the analysis segment (AS; in-stent plus 5 mm proximal and distal) was performed.
Results: In patients assigned to angiographic restudy, diabetes was present in 25.8% of patients, the reference vessel diameter was 2.8 mm, and the average lesion length was 14.4 mm. At late angiographic follow-up, there were significant reductions in all parameters of late lumen re-narrowing with the use of the paclitaxel-eluting stent:

Follow-up QCA	Control Stent (N=357)	TAXUS Stent (N=375)	P value
MLD, IS/AS	1.75 / 1.68	2.26 / 2.03	< 0.001/<0.001
Edge, Proximal/Distal	2.51/2.25	2.58/2.34	0.20/0.04
% Stenosis, IS/AS	37.2 / 39.8	17.4 / 26.3	<0.001/ < 0.001
Late Loss, IS/AS	0.92 / 0.61	0.39 / 0.23	< 0.001 / < 0.001
Loss Index, IS/AS	0.56 / 0.48	0.23 / 0.38	< 0.001 / < 0.001
Binary Restenosis, IS/AS	24.4/ 26.6	5.5 / 7.9	< 0.001 / < 0.001

Conclusions: We conclude that restenosis within the stent, within its 5-mm proximal and distal edges, and within the analysis segment is significantly reduced with the use of the paclitaxel-eluting stent.

2:45 p.m.

843-4

Reduction in Late Loss and Restenosis in Patients With Small Vessels Treated With the Slow Rate-Release, Polymer-Based Paclitaxel-Eluting Stent: Results From TAXUS-IV

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Background. The relative efficacy of the polymer based paclitaxel slow release eluting TAXUS stent in small vessels with de novo lesions is unknown.
Methods. In the TAXUS-IV trial, 1,314 patients with de novo lesions ranging from 2.5 – 3.75 mm in diameter and 10-28 mm in length were randomized to treatment with the slow rate-release, polymer-based paclitaxel-eluting TAXUS stent (n=662) vs. an identical appearing uncoated EXPRESS stent (n=552).
Results. Of 1381 implanted stents, 424 (31%) were 3.5 mm in diameter, 669 (48%) were 3.0 mm diameter, and 288 (21%) were 2.5 mm in diameter. For the entire study population, the TAXUS stent reduced the 9-month TLR and RR from 11.3% with BMS to 3.0%, and from 26.6% to 7.9% respectively (both P<0.0001). As seen in the table, both TLR and RRs progressively rose with decreasing stent size among patients receiving BMS. In contrast, TLR and RRs were independent of stent size with the TAXUS stent. Among BMS pts, absolute LL was independent of stent size, whereas with TAXUS, LL was significantly less in smaller stents.

9 month rates by stent diameter	Control	TAXUS	P value
TLR – 2.5 mm	18.0%	3.1%	0.0001
TLR – 3.0 mm	11.5%	3.7%	0.0002
TLR - 3.5 mm	7.3%	1.0%	0.002
RR – 2.5 mm	40.8%	8.8%	0.0002
RR – 3.0 mm	31.2%	9.1%	<0.0001
RR – 3.5 mm	12.9%	5.5%	0.13
LL – 2.5 mm	0.65 mm	0.17 mm	<0.0001
LL – 3.0 mm	0.61 mm	0.22 mm	<0.0001
LL – 3.5 mm	0.60 mm	0.28 mm	<0.0001

Conclusions. The paclitaxel-eluting TAXUS stent markedly reduces restenosis, independent of vessel size, with reduced late loss and the greatest relative efficacy seen in the smallest vessels.

3:00 p.m.

843-5

Drug-Eluting Stents for the Treatment of Bifurcated Coronary Lesions: A Randomized Comparison of Simple Versus Complex-Strategy Approach

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Background: Rapamycin-eluting stents (RES) have shown to reduce restenosis in many types of lesions. However, to date, the full reconstruction with RES of the entire bifurcation has not been proven to improve the results of a simple strategy. **Methods:** To compare both strategies we carried out a randomized study in 91 patients with true coronary bifurcation lesions. All patients received a RES at the main vessel, covering the side branch (SD). Patients from group A (n=47) were assigned to balloon dilation of the involved SD (simple strategy); 44 patients (group B) were randomized to receive a second stent at the SD origin (complex strategy). There were no differences between groups regarding baseline clinical and angiographic data. One patient from group A crossed-over to complex strategy due to a poor immediate result, whereas it was impossible to implant a stent at the ostium of the SD in 4 patients from group B, so the intervention was limited to balloon dilation. **Results:** The table summarizes the immediate and follow-up results on an intention to treat basis. Six-month angiographic reevaluation was obtained in 67 patients. Restenosis of the main vessel was observed in one patient from group A (3%) and in 2 from group B (6%). Restenosis of the SD appeared in 2 patients from group A (6%) and in 4 from group B (13%). **Conclusions:** Both strategies are effective, without any differences in terms of clinical outcome. Elective SD stenting seems to provide no advantages over the simpler stent jail followed by SD balloon dilation. .

Immediate and follow-up results

	Non-Q myocardial infarction	Death	Target lesion revascularization	Total major cardiac events at 6 months
Group A (n=47)	2 (4%)	0	1 (2%)	3 (6%)
Group B (n=44)	0	1(2%)	2 (5%)	3 (7%)

3:15 p.m.

843-6

Three-Year Follow-Up of the RAVEL Study: A Randomized Study With the Sirolimus-Eluting Bx VELOCITY™ Stent in the Treatment of Patients With De Novo Native Coronary Artery Lesions

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Background: Sirolimus, a macrocyclic antibiotic and immunosuppressant, causes late G1 cell cycle arrest. A pilot study using Sirolimus-eluting stents to treat coronary artery lesions demonstrated almost no neointimal hyperplasia at 12 months. Results from this study were used to design RAVEL, a multicenter, double blind, two-arm, randomized study assessing safety and effectiveness of the Sirolimus-Eluting BX VELOCITY™ stent versus the uncoated Bx VELOCITY™ stent (18 mm).
Methods: The primary endpoint was angiographic late loss at 6 months. The secondary endpoints were major adverse cardiac events, target vessel revascularization (TVR), target lesion revascularization (TLR) and restenosis rate. Inclusion criteria: stable or unstable angina, single treatment-de novo lesions < 18mm long, 2.5-3.5 mm diameter. Clopidogrel or Ticlodipine was continued for up to 8 weeks following a loading dose.
Results: From August 2000-December 2000, 238 patients were enrolled at 19 sites in